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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,626	05/24/2002	Akihiho Maruyama	P21989	7767
7055	7590	08/10/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,626	MARUYAMA ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 21-43 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-20 in the reply filed on May 23, 2005 is acknowledged. The traversal is on the ground(s) that “[A]pplicants respectfully request that the Examiner reconsider the requirement in as much as it appears that it would not be a serious burden to search the art encompassing all of the claims. It appears from the restriction requirement that the Examiner has already conducted a search of subject matter related to Group II by noting a specific reference related to the subject matter therein. Accordingly, it would not appear to be a serious burden further Examiner search the subject matter related to Group I in combination with Group II, or similarly to search all Groups combined”.

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I, II, and III will be examined together. Since this instant case is a 371 case, the restriction is not dependent on search burden but is based on that Groups I and III and Group II do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features (see previous office action). Furthermore, the restriction on Groups I and III is based on that Groups I and III do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features. For example, step 2) of claim 1 in Group I is not required for Group III while genus *Cycloclasticus* in Group III is not required for Group I (see previous office action). Therefore, the requirement is still deemed proper and is therefore made FINAL and claims 1-20 will be examined.

Claim Objections

2. Claim 1 is objected to because of the following informality: "under the conditions under" in step 1) should be "under the conditions".

3. Claim 2 is objected to because of the following informality: note that "MPN" is an abbreviation. This abbreviation can only be used after it appears once.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for performing the method recited in claim 1-8, does not reasonably provide enablement for performing the methods recited in claims 13-18 using the methods as claimed in claims 3-8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the

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prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance in the specification to perform the methods recited in claims 13-18 using the methods as claimed in claims 3-8. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether the methods recited in claims 13-18 can be performed using the methods as claimed in claims 3-8.

Claims 13-16 are directly to a method for analyzing and evaluating a polluted environment by harmful chemicals using the method as claimed in claims 3-6 while claims 3-6 are directed to a method for detecting and quantitating a micro-organism having a specific function from a natural environment wherein the micro-organism having a specific function can degrade a specific chemical substance such as a harmful chemical substance. However, in view of claims 3-6, it is unclear how to analyzing and evaluating a polluted environment by harmful chemicals using the micro-organism having a specific function recited in claims 13-16 since claims 3-6 do not have a step for analyzing and evaluating a harmful chemical. Claims 17 and 18 are directed to a method for analyzing and evaluating an oil polluted environment using the method as claimed in claims 7 and 8 while claims 7 and 8 are directed to a method for detecting and quantitating a micro-organism having a specific function from a natural environment wherein the micro-organism having a specific function can degrade a specific chemical substance such as petroleum and petroleum components. However, in view of claims 7 and 8, it is unclear how to analyzing and evaluating an oil-polluted environment by using the micro-

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organism having a specific function recited in claims 17 and 18 since claims 7 and 8 do not have a step for analyzing and evaluating petroleum and petroleum components. Furthermore, since an oil-polluted environment is not limited to an environment polluted by petroleum and petroleum components, the micro-organism having a specific function recited in claims 7 and 8 may not be used to degrade all oil-polluted environment which is not polluted by petroleum and petroleum components. Therefore, in view of claims 3-8, it is unpredictable whether the methods recited in claims 13-18 can be performed using the method as claimed in claims 3-8.

With these unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. These undue experimentations at least includes to test whether the methods recited in claims 13-18 can be performed using the methods as claimed in claims 3-8.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is rejected as vague and indefinite in view of the preamble of the claim because it is unclear what means " a microorganism having a specific function and its gene from the natural environment". Furthermore, the phrase "the natural environment" lacks insufficient

antecedent basis since there is no phrase “a natural environment” before “the natural environment”. Please clarify.

9. Claim 1 is rejected as vague and indefinite in view of step 1) of the claim because it is unclear that heterotrophic microorganisms are in a microorganism-containing sample or not. If heterotrophic microorganisms are not in a microorganism-containing sample, the phrase “the total number of heterotrophic microorganisms” lacks insufficient antecedent basis. Furthermore, the phrase “the dominant level of the microorganism having a specific function” lacks insufficient antecedent basis since there is no phrase “dominant level” before “the dominant level of the microorganism having a specific function”. Please clarify.

10. Claim 1 is rejected as vague and indefinite in view of step 2) of the claim because the phrase “the microorganism in a liquid culture broth of the highest dilution ratio at which the growth of the microorganism is judged as positive” lacks insufficient antecedent basis since step 1) does not indicate that the microorganism is in a liquid culture broth. Please clarify.

11. Claim 1 is rejected as vague and indefinite in view of step 3) of the claim because it is unclear what means “examining the difference of the gene domains thus cloned” since the step 3) does not indicate what is used to compare with the gene domains thus cloned. Please clarify.

12. Claims 9 and 10 recite the limitation “the natural environment” and “the microorganisms” in the claims. There is insufficient antecedent basis for this limitation in the claims because there is no phrase ““the natural environment” and no word “microorganisms” before “the natural environment” and “the microorganisms”. Please clarify.

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Conclusion

13. No claim is allowed.
14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
August 5, 2005


FRANK LU
PATENT EXAMINER